#### SYSTEM AUDIT REPORT NUMBER 04/35812/AS-S04



#### THIS REPORT RELATES TO A/AN SURVEILLANCE VISIT ON NOVEMBER 16-17, 2004

Company: Marshal Space Flight Cen	nter		Other Sites Visited: 1. N/A			
Address: Marshall Space Flight Cen	iter, A L 35812		2. N/A			
Agency Infrastructure and is a	Major Contribunt, Production, In	tor to All Its Scientif nstallation and Service	ing of Flight Hardware, Flight Software, and			
Standard(s): AS 9100B	Support Docu	mentation(s): AS91	01B Non-English Languages Used: N/A			
Comments/Concerns of the Assessm Noncompliances noted are mit Six Previously identified none Recommend continued registr	nor in nature compliances have		nd 3 have been satisfactorily addressed.			
The visit is deemed to be:  Satisfactory Unsatisfactory Unsatisfactory visits may result in a chang audit activity.	ge to the next	Corrective Action Plan (CAP) Instructions:  Return CAP in 20 working days (all NCs, Obs & OIs). Certificate processing initiates after receipt/acceptance of CAPs.  AS & QS-9000 NCs must be closed prior to certificate issuance.  Return CAP in ten days for Major NCs issued during surveillance.				
NQA ASSESSMENT TEAM			COMPANY INFORMATION			
LEAD AUDITOR: Rick Giguere			MGT. REP.: Robin Henderson			
TEAM: Trudy Keaveney	TEAM:		QUALITY MANUAL (REV & ISSUE DATE):			
TEAM:	TEAM:		Rev. N Sept 17, 2004			
The state of the s	wat not be distant	to a third mark with and al-	a prior agreement of NOA IISA and the company named			
above. Non-compliances/non-conformances rai compliances/non-conformances may exist which report. The company representative's signature	ised or observations in the have not been identified in indicates their agrees	noted within this report are tified. The Internal Audit ment and understanding o	e prior agreement of NQA, USA and the company named the result of limited sampling and therefore non- system is deemed effective unless noted within the body of this f any non-compliances/non-conformances and observations			

C1403/01-24-03/E

Company Representative Signature and Date:

documented. The quality system shall be understood throughout the organization.

#### SYSTEM AUDIT REPORT NUMBER: 04/35812/AS-S04



#### **AUDIT MATRIX**

through entire box	reference point for assessment. X or √ x as applicable to indicate actual		SPEC	TFIC	ISO 9					MENT IG TH			ONS/	PRO	CESS	ES	NEXT VISIT PLAN
requirement. X or	udited against the ISO 9001:2000  √ in next visit block indicates planned stivity. Estimated duration is 45 minutes.	Į g	r								13						
Note: Asterisk (*) activity.	) indicates requirement to be reviewed at each	nent Re				Audit		4			ens Ass						
ISO 9001:2000 Reference	Clause Title	Management Rep	МОС	PMC	MTM	Internal Audit	HEI	SSME	ISPT	NODE II	DART Lens Assy			77.00			AS-S05
4.2.1 & 4.2.2*	Quality Manual *	X															X
4.2.3	Document Control																X
4.2.4	Quality Records		X	X	X	X	X	X	X	Х	Х						
4.1, 5.1, 5.2, 5.3, 5.4.2, 5.5	Management Activities																X
5.4.1*	Quality Objectives*	X	X	X	X												X
5.6*	Management Review *	X	X														X
6.1 & 6.2	Resources & Competence																
6.3 & 6.4	Infrastructure & Work Environment									,							
7.1	Product Realization Planning						,		X	X	X						
7.2	Customer Related Process & Comm.								X	X	Х	•					
7.3	Design & Development																
7.4	Purchasing				·												
7.5.1 & 7.5.3	Process Provision and ID&T Activities										•						
7.5.2	Process Validation				-										-		Х
7.5.4	Customer Property																X
7.5.5	Preservation (Handling, Storage & Deliv.)																X
7.6	Calibration																X
8.1	Measurement & Monitoring Planning								X	Х	X		Ĩ				
8.2.1*	Customer Satisfaction*	X	X	X	X												X
8.2.2*	Internal Audits*					X											X
8.2.3	Measurement & Monitoring of Process																
8.2.4	Measurement & Monitoring of Product																
8.3	Non-Conforming Processes/Products																X
8.4	Analysis of Data		Х	X	X												X
8.5.1*	Continuous Improvement*		Х	X	X												X
8.5.2 & 8.5.3*	Corrective/Preventive Action*		n siğene Lita	X		X	X	X		a their as							X
	Use of NQA Logo	Х															X

No. History Co.

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#### SYSTEM AUDIT REPORT NUMBER 04/35812/AS-S04



#### SYSTEM AUDIT RECORD

Auditor(s): Rick Giguere Trudy Keaveney

Date: November 16, 2004

Clause No.	Record of Details of Audit (names, referenced documents, depts, etc.)	NC	Obs or OIs
4.2.1,	See AS9101B checklist for details	1	1
4.2.2,	INTERVIEWED: DOCUMENTS REVIEWED:		_
4.2.4	OBJECTIVE EVIDENCE SAMPLED:		
			,
5.4.1,	See AS9101B checklist for details	1	Í
5.6	INTERVIEWED: DOCUMENTS REVIEWED:		
	OBJECTIVE EVIDENCE SAMPLED:		
			,
7.1, 7.2	See AS9101B checklist for details INTERVIEWED:	2	
	DOCUMENTS REVIEWED:		
	OBJECTIVE EVIDENCE SAMPLED:		
8.1,	See AS9101B checklist for details	3	1
8.2.1,	INTERVIEWED:		1
8.2.2,	DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:		
8.4, 8.5	OBJECTIVE EVIDENCE SAIM BED.		
0.4, 6.5			
:		1	

Party.	TOTAL	7	2
	PAGE 3 OF	4	

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#### SYSTEM AUDIT REPORT NUMBER 04/35812/AS-S04



Ref No.	Clause No.	NON-CONFORMANCES & OBSERVATIONS/OPPORTUNITIES FOR IMPROVEMENT RAISED	NC/OBS OI
1	4.2.3	Test Discrepancy Reports are not completed in a consistent manner.	OBS
2	7.4	Qualification criteria, thresholds of performance and consequences of poor performance have not been identified.	NC
3	7.4	Required actions when issued during supplier audits that introduce a potential risk are not identified. Ref: Sierra Lobo NDE Audit item#11, General finding polyolefin and nylon in space flight application, omission of mettallographic inspection in work instructions.	NC
4	8.5.2	Supplier corrective actions do not demonstrate full root cause corrective action anlysis. ref: Sierra Lobo audit finding corrective actions.	NC
5	8.5.2	Corrective actions are not consistantly appropriate to the effects of the nonconformity. Inconsistant root cause identification. ref; RCAR 219&222	NC
6	8.2.2	The go-forward audit schedule for 2005 ia still a work in process due to the transformation process.	OBS
7	5.6	MPG 7120.4 Appendix I: PPA Monthly Health Status Report requires that root cause of any yellow or red condition and recovery plan be described. A review of these reports reveals inconsistencies in the reporting of cause analysis and recovery plans in roughly half of the projects/programs reporting.	NC
8	4.3	MPG 8040.1, Configuration Management, MSFC Programs/Projects, Par. 3.4.2 states that Each program and/or project office shall ensure that periodic CM system audits of in-house CM activities be conducted. A review of CM audits reveals that it is CM itself that initiates these audits, and not the program or project office. Certain programs, such as Solar B and Dart, have declined audits.	NC
		(Continued from above)It is not likely that CM audits would be conducted without the initiative of the CM group.	
-			

. / 1 / 21 / 21			4 + 6 4	
NQA/USA Répresentativ	e Signature and Date:	Company Repr	esentative Signature and Da	Page 4 of 4
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C1405/01-24-03/E



### **AEROSPACE** STANDARD

Technically equivalent to AECMA prEN 9101

REV. В

Issued Revised 2000-09 2003-03

Superseding AS9101A

Quality Management Systems Assessment

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#### FOREWORD

In December 1998, the Aerospace Industry has established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream.

This organization, with representation from Aerospace companies in Americas, Asia and Europe and sponsored by SAE, SJAC and AECMA has agreed to take responsibility for the technical contents of this standard.

#### DAE ADDITI Kevision B

### CONTENTS

#### QUALITY MANAGEMENT SYSTEMS - ASSESSMENT

1	Purpose			÷Ÿ	 	5
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2	Quality system	assessm	ent report conte	ent	 	5
				,		40
Appendix A	Quality system	questioni	naire		 •	13
Bibliography	•••••	<del> </del>	***************************************		 	47

### **SECTION 1**

# QUALITY MANAGEMENT SYSTEMS ASSESSMENT

#### 1 PURPOSE

The purpose of this document is to define the content and the presentation of the Assessment Report of the section 1 of AS9100.

#### 2 QUALITY SYSTEM ASSESSMENT REPORT CONTENT

The Assessment Report is made up of:

- Page 6 (reguired)
   General Assessment Information
- Page 7 (required)
   Assessment Conclusions
- Page 8 (optional)
   General Organization Information
- Page 9 (required)
   Assessment Result Summary
- Page 10 (required)
   Assessment Scoring
- Page 11
   Corrective Action Request (when required)
- Page 12
   List of Recommendations/Observations/Comments
- Appendix A
   Quality System Questionnaire relative to the section 1 of AS9100

Assessing company logo

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Huntsville, AL 358 Main activities: Testing Product Types or Codes:	* ' '			<u> </u>			
2 ISO Registration	· · · · · · · · · · · · · · · · · · ·	·					
[ /] ISO Registered				Neq-usa			
[ ] ISO Standard / Revision			Expiration Date (If app	olicable): 5/2	77		
Aerospace Standard / Rev	ision AS9160B			-	<del></del>		
3 Assessment Team							
Lead Assessor Name: Rick	#03158		Other Assessor Team				
Certified Auditor – Type &	No. Q03158		TRUDY KEHU		Opp	/ 11	
[ ] Qualified Auditor		·	·	A05611,	4050	011_	/
4 Assessment Dates:	Nov	16-	17,04	· · · · · · · · · · · · · · · · · · ·	····		
5 Assessment Scope	· · · · · · · · · · · · · · · · · · ·	<del></del>	#				
[ ] Total facility assessed	[ ] Initial assess		[ ] All 9100 elements	* · · · · · · · · · · · · · · · · · · ·			,
Partial facility assessed	[ ] Re-assessm	nent	[ Partial 9100 eleme	nts assessed	5150	5.30	5.4.2
[ ] Other:			[ **Partial 9100 eleme Elements not assesses 5.5, 6, 7.3, 7.4, 7.5,	7.6,8,2.3,	8.2.4,8	3	
[ ] Activity assessed:		- 1					
6 Assessment Disposition	<u> </u>		7 Scoring				
[ ] Conforming		-	Scoring result:				
[ Conforming with minor (mi)							
[ ] Non conforming with Major	(MA) corrective ac	tion					
8 Assessment Approval	Γ		l A		Cianoturo		
Assessing Company	Date	L∈	ead Assessor Name	10.000	Signature		-
NQA-USA	NOV 17, 04	Rich	lard Siguere	Kick of	9	,	
					<u> </u>		

#### Distribution Agreement

This Assessment Report is the property of the assessed Organization and the assessing Company. Distribution to other companies or individuals is authorized only after written agreement of the assessed Organization and of the assessing Company.

To that end, a signature below by an Authorized Representative of the assessing company indicates that this report may be copied by the organization for other customers.

- 6 -

If copied, the report must be disclosed in full including findings and any chapter and Representative Kick Giguere

100 (Major) STATEMENT OF THE

Assessing Company Name

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Signature

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Assessing company logo

#### ASSESSMENT CONCLUSIONS

General comments about the organization and the quality system of the assessed organization:

Strong points:

- Rish Management fracess
- Adaptability eferganization to external influences

Improvement Opportunities:

- Greater emphasis on development of process performance measures

Assessing company logo

		#11	17 (19 m)	the state of the s
	GENERAL ORGANIZA	ATION INFORMA	e projection and the second	
1 Legal and Financial A	spects			
☐ Date of Formation:		15世代   15世代		
☐ Legal Status: ☐ Capital:				
☐ Other Data:				
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Sales				
Earnings			· · · · · · · · · · · · · · · · · · ·	
Earnings used for Re- Investment				(
Workforce		ž		
2 Turnover breakdown a	nd main Customers			
Activities	Main Custome	rs	Sales Percenta	ige
Aircraft, Space and Defense Industry				
Other Activity (be specific)				
3 Clearances or Approva	ls granted by Authorities			- 4
Name of the Authority	Types and Referen	ices	End of Validit	y
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	Quality management system			05		(50)	ED
4.1	General requirements	0:	10	25 25	40	50	30
4.2 & 4.3	Documentation requirements & Configuration management  Management responsibility	0		25	40	<del>-i</del>	10
5.1	Management commitment	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		<u>, 'K , , 5° 6' al</u>			1 10 10 10 10
5.2	Customer focus	-		** . *			
5.3	Quality policy	0	5	15	20	(30)	30
5.4	Planning	0	10	20	30	402	40
- 5.5	Responsibility, authority and communication	0	5	15	20	(30)	30
5.6	Management review	0	10	25	(40)	50	40
355° € 6	Resource Management		运通行动	HEREN SERVICE		图(100)	法国籍的
6.1	Provision of resources	0	10	25	40	(50)	~0
6.2	Human resources						50
6.3	Infrastructure	0	10	25	40	(50)	50
6.4	Work environment	Tableton received for	No Produced February	eringe v 12407	Che Pallana.	SOUTH FANCES	
7	Product realization.					(450)	77
7.1	Planning of product realization	0	5	15	20	(30)	70
7.2	Customer related processes	0	10	30	50	(60)	-60
7.3	Design and development	0	5	15	20	(30)	201
7.3.1	D& D Planning Inputs, outputs & review	0	5	15	20.	(30)	30
7.3.5-6		0	5	15	20	30	20
7.3.7	Control of design and development changes	0	. 5	15	20 0	(30)	30
7.4	Purchasing	0	. 10	(30)	(XXX	60	20
7.5	Product and service provision	1.05	14.00.2.155		0		
- 7.5.1	Control of production and service provision	0	10	25	40	(50)	50
7.5.2	Validation of processes for production and service provision	0	10	20	30	40	40
7.5.3	Identification and traceability	0	10 -	20	30	(40)	40
7.5.4-5	Customer property & preservation of product	. 0	5	15	20	(30)	30
7.6	Control of monitoring and measuring device	0	5	10	15	(20)	20
8	Measurement analysis and improvement		<b>产工会计算</b>			(200)	01
8.1	General	0 1	5	10	15	(20)	20
8.2	Monitoring and measurement			· .	45	/20	00
8.2.1	Customer satisfaction	. 0	5	10	15 20	30	30
8.2.2	Internal audit	0	5	15 15	20 .	(30)	20
8.2.3 8.2.4	Monitoring and measurement of processes  Monitoring and measurement of product	0	5	15	20 .1	(30)	20
8.3	Monitoring and measurement of product  Control of nonconforming product	0	5	15	20	(30)	20
8.4	Analysis of Data	0	5	10	. 15	(60)	20
8.5	Improvement	0	5	(O)	(B)	20	
	The state states to the state				TOTAL	880 <sup>(1)</sup> or	air
		<u> </u>			TOTAL	1000	110
The assess	ed Organization agrees on the Quality System scoring and Cor	rective Actio	on .		SCORE	0111/10	al
requests		<del></del>			000.12	110,10	

(1) -When 7.3 is not assessed : SCORE = RESULT X 100-

Organization Representative :

Date:

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	Organization : $NASA$	MS	FC	)	Hu	entsville AL			70% 1000 1000 1000 1000 1000 1000	
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1	4.1 General requirements									
1	4.2 Documentation requirements	1				loks		-		
1	4.3 Configuration Management			1				·		
1	5 - Management responsibility	-								
1	5.1 Management commitment						<i>;</i>			
5	5.2 Customer focus									
5	5.3 Quality policy									
5	5.4 Planning									
5	5.5 Responsibility, authority and communication									
5	5.6 Management review									
E	6 - Resource management								33	
6	3.1 Provision of resources									4.
6	3.2 Human resources									
-6	3 Infrastructure								. C. Flatterina	
6	.4 Work environment				<u> </u>					
7	- Product realization		·							
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7	.3 Design and development									
7.	.4 Purchasing			2					·	
	.5 Production and service provision									
7.	6 Control of monitoring and measuring devices									
8	- Measurement, analysis and imp	roven	nent							
8.	1 General						·			
8.	2 Monitoring and measurement					10ks				
8.	3 Control of nonconforming product									
8.	4 Analysis of data						<u> </u>			
8.	5 Improvement			2						
	ssessed Organization:  NASA MSFE		A. Pro-	6		Assessing Company: Lead Assessor Name:			auele	
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<sup>\*</sup> For each element, cross results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor or "N/A" for non applicable

# CORRECTIVE ACTION REQUEST (C.A.R.)

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### APPENDIX A AS9101

QUALITY SYSTEM QUESTIONNAIRE

#### 1. PURPOSE

The purpose of this document is to present the questionnaire to be used during the "on site" quality system assessment of Organizations in order to ensure common practices for these assessments. This questionnaire is relative to the section 1 of AS9100.

#### 2. USE OF THE QUESTIONNAIRE

The use of this questionnaire is mandatory and will be a part of the Assessment Report. The questionnaire is used to evaluate AS9100 standard, section 1.

The audit is undertaken by review against the requirements of the questionnaire and the findings are recorded as appropriate by annotation of respective columns,

- > Satisfactory (S)
- > Not applicable (N/A) the reason shall be documented in the bottom of the page
- > Not evaluated (N/E)
- > Corrective Action Request (CAR) Major (Ma) or Minor (mi.) finding:

The CAR number shall be referenced in the column "CAR number"

The category Ma for Major CAR or mi for Minor CAR shall be included in this column also.

#### Additional information on questionnaire

Key Requirements: Some requirements are deemed to be very significant and are so identified by the presence of 'P' or 'M' against the specific section or question within the questionnaire,

"P" direct link with product

"M" direct link with Management

The extent of Key Requirement applicability is determined by the location of the 'M' or 'P'. In the example below all of question 14 is considered as a key requirement.

ſ	14	Does th	ne output from the management review include any decisions and actions related to :	М			
			Improvement of the effectiveness of the quality management system and its processes ?				
		b)	Improvement of product related to customer requirements? and				
		c)	Resource needs?				

In the second example below only part of question 03, i.e. d) is considered Key Requirement.

03	in plai	nning product r	ealization, does	s the organization	determine the fo	ollowing, as approp	oriate:			
	a)	Quality object	tives and requi	rements for the pro	oduct?					
	b)	The need to	establish proce	sses, documents,	and provide res	ources specific to	the			
		product?	Alma Comment	1. 10 May 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.			100	19.00		
	c)	Required veri	fication, validat	tion, monitoring, ins	spection and te	st activities specifi	c to the			
		product and t	he criteria for p	roduct acceptance	?	1.30				
	d)	Records need	ded to provide e	evidence that the re	ealization proce	sses and resulting	product P	,		
tie. Se	· .	meet requirer	nents (see 4.2.	4) ?		A Section of Section 1997		Allanda Allanda		. (
fig.,	e)	The identifica	ntion of resoul	ces to support of	peration and m	aintenance of the	e # ##	eres Zunije e Resignita zi		Park S
<b>3</b> 5	1940 1940 1940	product?	and the state of t			<b>一直</b>			100 mg 10	

Guidance notes. Certain questions will have a numeric reference that refers to additional guidance notes which are detailed within the 'Guidance notes' section located after the questions on each page. The guidance notes provide the Auditor with further insight on type of objective evidence and/or review expectations etc. In the example below, note (1) refers the auditor to additional notes pertaining to question 1 part a).

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	48 Does	s the analysis of c	lata provide informati	on relating to	):	The second secon		177 187 (197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197 - 197	
	a)		action (see 8.2.1) (1)	100 mg/m		1465 - 1570 -			in a
1 (1/46 ). 14 (1)	b)		oduct requirements (	3.5			The art of the second s		
Prists	c) _	Characteristics a	and trends of process	es and produ	ucts including oppor	tunities for prev	entive		
	e de la companya de l	action ? And		1000 1000 1000 1000		- 1 A			
	d)	Organizations?	1 X	34 m				al in	 14.

#### Guidance Note

1) Give examples and check how the organization measures the effectiveness.

<u>References</u>: When a reference (e.g. 4.1) is added to a question, It is linked to the appropriate chapter (e.g. 4.1) of AS9100.

Objective evidence assessed / Observations / Comments / N/A explanation Record the objective evidence reviewed during the assessment or reason for not applicable.

#### Non-conformities:

Major: The absence of, or total breakdown of a management element specified in the 9100 standard or any non-conformities where the effect is judged to be detrimental to the integrity of the product or service.

Minor: A single system failure or lapse in conformance with a procedure relating to the 9100 standard.

**Note**: A number of minor non-conformities against one requirement can represent a total breakdown of the system and this can be considered as a major non-conformity

#### USE OF THE ASSESSMENT SCORING CHART

Following completion of each chapter of the Quality System Questionnaire the nomenclature Assessment Scoring chart can now be completed.

The findings of each section and sub-section of the completed Quality System Questionnaire are reviewed and the Assessment Scoring sheet completed as follows.

- ➢ If, multiple findings (i.e. greater than 1) with Major (Ma) Corrective Action Request (CAR) or minor (mi) CAR on Key requirement in a section, e.g. 4.1 General Requirements then score in Major CAR or minor CAR on Key Requirement (i.e. any questions with 'M' or 'P' indicator) "Multiple findings" column (result = 0), or
- ▶ If, single finding with Major (Ma) CAR or minor (mi) CAR on key requirements in a section, e.g. 4.1 General Requirements then score in Major CAR or minor CAR on Key Requirement "Single finding" column (result =10), or
- If, multiple findings on non Key requirement (i.e. greater than 1) with Minor (mi) (CAR) in a section, e.g. 4.1 General Requirements then score in Minor CAR on non Key requirement "Multiple findings" column (result=25), or

- ➢ If, single finding on non Key requirement with Minor (mi) CAR in a section, e.g. 4.1 General Requirements then score in Minor CAR on non Key requirement "Single findings" column (result = 40), or
- When a single finding occurred on several questions affecting the same section of the scoring table (e.g. 4.2 & 4.3 or 5.1-5.2-5.3), then score as "multiple findings".

Further notes on scoring

The above review criteria should be considered sequentially.

Maximum audit total can be,

1000, where audit review comprises whole Quality System Questionnaire or,

880, where audit review comprises Quality System Questionnaire less Design and Development. In this case, the final score = TOTAL X 100

880

If a complete section line of the score sheet has not been assessed (N/A or N/E) the score will be calculated as follow:

Score = TOTAL x 100
Score = Sum of maximum possible score

The higher the score the greater the level of compliance acknowledged by the audit activity.

State Section

## Summary

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1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Section headings	1.10 T.		Page numbers
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4.1	General requirements	T.	The state of the s	18
4.2	Documentation requirements	. 8 (2) - 27 (2) (2) - 27 (2) (3) - 27 (2) - 27 (2) - 27 (2)		19 – 20
5	MANAGEMENT RESPONSIBILITY			21
5.1	Management commitment	iji polici.	A Company of the Comp	21
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8	MEASUREMENT, ANALYSIS AND IMPROVEME	NT		40
8.1	General			4
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8.4	Analysis of data			45
8.5	Improvement			46

ASSESSMENT QUESTIONS  4 • QUALITY MANAGEMENT SYSTEM  4.1 General requirements  01 Has the organization established, documented, implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard?  02 Does the organization:  a) identify the processes needed for the quality management system and their application throughout the organization (1)?  b) determine the sequence and interaction of these processes (1)?	
4.1 General requirements  01 Has the organization established, documented implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard?  02 Does the organization  a) identify the processes needed for the quality management system and their application throughout the organization (1)?  b) determine the sequence and interaction of these processes (1)?	N/E
01 Has the organization established, documented implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard?  02 Does the organization  a) identify the processes needed for the quality management system and their application throughout the organization (1)?  b) determine the sequence and interaction of these processes (1)?	· (
management system and continually improve its effectiveness in accordance with the requirements of this International Standard?  02 Does the organization:  a) identify the processes needed for the quality management system and their application throughout the organization (1)?  b) determine the sequence and interaction of these processes (1)?	
a) identify the processes needed for the quality management system and their application throughout the organization (1)? b) determine the sequence and interaction of these processes (1)?	
a) identify the processes needed for the quality management system and their application throughout the organization (1)?      b) determine the sequence and interaction of these processes (1)?	
c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective? d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes? e) monitor, measure and analyze these processes? and f) implement actions necessary to achieve planned results and continual improvement of these processes?	
03 Are these processes managed by the organization in accordance with the requirements of this international Standard?	
04 Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes?	<i>J</i>
05 Is the control of such outsource processes identified within the quality management system?	<u> </u>

<u>Note</u>: Processes needed for the quality management system referred to above should include processes for management, provision; product realization and measurement.

#### Guidance Note

1) Main process formally identified e.g.: list, flow diagram, etc.

Objective evidence assessed / Observations / Comments / N/A explanation

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S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE	Artes	
ASSESSMENT QUESTIONS	KEY Requirements	S CAR N/A N/E Number in Ma orm
4.2 Documentation requirements	all files	
4.2.1 General		
O6 Does the quality management system documentation include:  a) documented statements of a quality policy and quality objectives?  b) a quality manual?  c) documented procedures required by this International Standard?		
d) documents needed by the organization to ensure the effective planning, operation and control of its processes? e) records required by this International Standard (see 4.2.4)? and f) quality system requirements imposed by the applicable Regulatory Authorities?		
07 Does the organization ensure that personnel have access to quality management system documentation and are aware of relevant procedures ?		/ 10
08 Do Customer and/or regulatory authority representatives have access to quality management system documentation?		
4.2.2 Quality manual (Cer N. 9/17/04 MPD 13	280.1	
09 Has the organization established and maintained a quality manual that includes (1):  a) the scope of the quality management system, including details of, and justification for, any exclusions?  b) the documented procedures established for the quality management system, or reference		
to them, and when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2)?  c) a description of the interaction between the processes of the quality management system?		
	ns that the r	procedure is established.
Note 1: Where the term "documented procedure" appears within this International Standard, this mea	iio uior uio p	

documented, implemented and maintained.

Note 2: The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

a consideration project

- b) the complexity of processes and their interactions, and
- c) the competence of personnel

#### Guidance Notes

A Roll House

- Quality manual reference and issue
- Check the procedure list

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed recent changes in manual since last activity
see ? I and & I for listing of seconds observed Verfield access to documentation

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management 一 海外都治。

ASSESSMENT QUESTIONS  ASSESSMENT QUESTIONS	N/E
4.2.3 Control of documents  10 Are the documents required by the quality management system controlled?  M	
10 Are the documents required by the quality management system controlled?	/
10 Are the documents required by the quality management system controlled?	/
11 Are records controlled according to the requirements given in 4.2.4?	$\overline{}$
12 Has a documented procedure been established to define the controls needed to :  a) approve documents for adequacy prior to issue ?	
b) review and update as necessary and re-approve documents? c) ensure that changes and the current revision status of documents are identified? d) ensure that relevant versions of applicable documents are available at points of use? e) ensure that documents remain legible and readily identifiable? f) ensure that documents of external origin are identified and their distribution controlled? and g) prevent the unintended use of obsolete documents, and to apply suitable identification to	
them if they are retained for any purpose ?	
13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements?	
4.2.4 Control of records	
14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?	
15 Do records remain legible, readily identifiable and retrievable (1)?	
16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?	_
17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers?	1
18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements?	
4.3 Configuration management	
19 Has the organization established, documented and maintained a configuration management P process appropriate to the product?	
Guidance Note  1) List records reviewed	

Objective evidence assessed / Observations / Comments / N/A explanation

Sangled record related to Dart Lens project, ISPT, + Nodes II See section 2.1 and 8.1 for records observed. Reviewed legibility of records, identificability, retrewalshifty, storage protection, relentin + desposition and supplier records. (certs)

4.2.3 Carrie over OBS#01

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

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4.2	Documentation requirements	36.884		1960 1960 1960	ı. ]
4.2.1	General	Taland Talanda Tanana	200 m		
06 Do a) b)	documented statements of a quality policy and quality objectives? a quality manual? documented procedures required by this International Standard?				
d) e)	documents needed by the organization to ensure the effective planning, operation and control of its processes? records required by this International Standard (see 4.2.4)? and quality system requirements imposed by the applicable Regulatory Authorities?			(V	
07 Do	nes the organization ensure that personnel have access to quality management system cumentation and are aware of relevant procedures ?		Take and the same of the same	V	
08 Do	Customer and/or regulatory authority representatives have access to quality anagement system documentation?		s	V	
4.2.2	Quality manual		<u> </u>	· · · · /	1.
09 Ha a) b)	the organization established and maintained a quality manual that includes (1): the scope of the quality management system, including details of, and justification for, any exclusions? the documented procedures established for the quality management system, or reference to them, and when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2)? a description of the interaction between the processes of the quality management system?	-	•		
- Page					

Note 1: Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

Note 2: The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and

c) the competence of personnel

#### **Guidance Notes**

- 1) Quality manual reference and issue
- 2) Check the procedure list

Objective evidence assessed / Observations / Comments / N/A explanation

Maturella Comments / N/A explanation

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S: Satisfactory— CAR: Corrective action required—Ma: Major corrective action—mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE			The Sales of the S	14	
ASSESSMENT QUESTIONS	KEY Requiremen	S Is	CAR Number Ma or mi	N/A	N/E
4.2 Documentation requirements (continued)		ondare To produce Policies	grand Type anthous The State		
4.2.3 Control of documents	distal		art Malia TAL		All Sales
10 Are the documents required by the quality management system controlled?	М			Τ	
11 Are records controlled according to the requirements given in 4.2.4 ?				1	ī
12 Has a documented procedure been established to define the controls needed to :	The state of the s	Jan.	6 100 to 1		
a) approve documents for adequacy prior to issue ?			Sugar Sugar The		
b) review and update as necessary and re-approve documents?	76.5		1		اسرا
c) ensure that changes and the current revision status of documents are identified?  d) ensure that relevant versions of applicable documents are available at points of use?	Tarih .				
e) ensure that documents remain legible and readily identifiable?			e de la companya de l		
f) ensure that documents of external origin are identified and their distribution controlled ? and		-			
g) prevent the unintended use of obsolete documents, and to apply suitable identification to	land,		es sens e		
them if they are retained for any purpose ?	10.			+	
13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements?				nia.	1
4.2.4 Control of records					
14 Are records established and maintained to provide evidence of conformity to requirements and		5			
of the effective operation of the quality management system?		2		-	
15 Do records remain legible, readily identifiable and retrievable (1)? majulet, are least	trances	0	···		<del></del>
16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?		5			
17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers Quellass		S		:	
18 Are records available for review by customers and regulatory authorities in accordance		5			
with contract or regulatory requirements? 200					
4.3 Configuration management ${\cal O}$	·		···		
19 Has the organization established, documented and maintained a configuration management	P		-	.	1
process appropriate to the product ?				<u> </u> -	
Guidance Note MTN metric board Al ) Qualit Connector	6 L A 1 L 18	TIE	us)		
Guidance Note MTM meeting records, Quality Capacit of List records reviewed Rules received Nescolus, Management received	w.	Ute	ndower	ro	Stek
	, c				
Objective evidence assessed / Observations/ Comments / N/A explanation/ National Values of Comments / N/A explanation/	treetin	ورم	Ble		
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		ASSESSMENT QUESTION	NS	grann. Gran - Grand Chap	KEY Requirements	Number Ma or mi
5	MANAGEMENT	RESPONSIBILITY		All Sections (All Sections (Al		ing and a second a
5.	1 Management coi	mmitment	No.		1. J	
01	implementation of the quali (1): a) communicating to the cand regulatory requirem	7 ~ (FPE) - 1	ntinually improving	its effectiveness by	7 (2007), the same of the same	
	<ul><li>b) establishing the quality</li><li>c) ensuring that quality ob</li><li>d) conducting managemer</li><li>e) ensuring the availability</li></ul>	jectives are established ? nt reviews ? And				
5.2	2 Customer focus					
02		red that customer requirements satisfaction (see 7.2.1 and 8.2.			44.	
5.3	Quality policy				1 4 July 1 4 3 3	
	<ul><li>b) includes a commitment to of the quality management</li><li>c) provides a framework for</li></ul>	pose of the organization?  to comply with requirements and ent system?  or establishing and reviewing qual aderstood within the organization	ality objectives ?	e the effectiveness		
5.4	Planning	in the second second	٠.			
5.4.	1 Quality objectives					
	requirements for product [se organization (3)?	sured that quality objectives, se 7.1 a)] are established at rel	levant functions an	needed to meet d levels within the		<i>3</i>
5.4.2		/	e quality pelley :	a fee		
06 F	rlas Top management ensuration the planning of the quality (see 4.1), as well as the b) the integrity of the quality	ed that:  management system is carried				· 4
1) E 2) lä	dance Notes Evidence of management coldentify and records method (Review objectives and status	of communication 1	ellexim;	<i>Rlementes</i>		
)bje	ctive evidence asses Network Yew Treary	ave leven 1.	71 -1		d rep	sted
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QUALITY SYSTEM QUESTIONNAIRE		
ASSESSMENT QUESTIONS	KEY Requirements	S CAR N/A N/E Number Ma or mi
5.5 Responsibility, authority and communication		
5.5.1 Responsibility and authority	(**) (**)	
07 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization (1) ?	and the second s	4
5.5.2 Management representative	400.00 4.40 4.40.00	
08 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:	M	
<ul> <li>a) ensuring that processes needed for the quality management system are established, implemented and maintained?</li> <li>b) reporting to top management on the performance of the quality management system and any need for improvement?</li> <li>c) ensuring the promotion of awareness of customer requirements throughout the organization? and</li> <li>d) the organizational freedom to resolve matters pertaining to quality?</li> </ul>		
5.5.3 Internal communication		the effect
09 Has Top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system ?		· · · · · · · · · · · · · · · · · · ·
Guidance Note		

Identify and records method of communication within the organization

Objective evidence assessed / Observations / Comments / N/A explanation

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S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

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QUALITY SYSTEM QUESTIONNAIRE			ra Mari
ASSESSMENT QUESTIONS	KEY Requirements	S CAI Numb Ma or	ber
.6 Management review	a suight spiegal th	in i	ijek
5.6.1 General HONONILLO MPR 1280.		And the	700
O Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness (1) ?	Supplied to the supplied to th		And the second
1 Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives ?		9	
2 Are records from management reviews maintained (see 4.2.4) ?	A Section		
.6.2 Review input		in the second	.55
Does the input to management review include information on (2):  a) results of audits?  b) customer feedback?  c) process performance and product conformity?  d) status of preventive and corrective actions?  follow-up actions from previous management reviews?  d) changes that could affect the quality management system? And review yellows the process performance and product conformity?  f) recommendations for improvement?	M	3	
g) recommendations for improvement?	1		
.6.3 Review output	M		
Does the output from the management review include any decisions and actions related to (2):  d) improvement of the effectiveness of the quality management system and its processes?  e) improvement of product related to customer requirements? And  f) resource needs?		5	
Records management review frequency and functions involved (e.g : quality, production, etc.) (A)  Verify the availability of input / output data such as: statistical data; graphics; summary tables; republicative evidence assessed / Observations / Comments / N/A explanation		· · · · · · · · · · · · · · · · · · ·	
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QUALITY SYSTEM QUESTIONNAIRE		And the second s	10.35
ASSESSMENT QUESTIONS	KEY Requiremen	s CAR Number Majormi	N/A N/E
6. RESOURCE MANAGEMENT	14 A 14 A 14 A	and the second of the second o	- 1 - <u>1</u> -
6.1 Provision of resources			46 (4) (4) (4) (4)
O1 Has the organization determined and provided the resources needed:  a) to implement and maintain the quality management system and continually improve its effectiveness? And  b) to enhance customer satisfaction by meeting customer requirements?	The state of the s		V
6.2 Human resources			4,1 )
6.2.1 General	790	7	
02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1)?	1976 - 1877 - 1878 -		Ĺ
6.2.2 Competence, awareness and training			
<ul> <li>Does the organization:</li> <li>a) determine the necessary competence for personnel performing work affecting product quality (2)?</li> <li>b) provide training or take other actions to satisfy these needs?</li> <li>c) Evaluate the effectiveness of the actions taken?</li> <li>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?</li> <li>e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3)?</li> </ul>	P		
6.3 Infrastructure			
<ul> <li>Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements?</li> <li>Infrastructure includes, as applicable:</li> <li>a) buildings, workspace and associated utilities?</li> <li>b) process equipment (both hardware and software)? And</li> <li>c) supporting services (such as transport or communication)?</li> </ul>			
6.4 Work environment			
05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements?	P .		V
Note: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanline	ss, protectio	n from electrostatio	:

Note: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

#### **Guidance Notes**

and production of the

1) Review training Records and Plan (status of the current year and of the previous year)

2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill, ...)

3) Review training certificates for the certified personnel and training records (internal and external training courses)

Objective evidence assessed / Observations / Comments / N/A explanation where ellers are this auditors Sukveillance (Utwitters)

		10 K 20 Ta 20 T	1.3/4/M	pries. Person		
QUALITY SYSTEM QUESTIONNAIRE		KEY	l s	CAR	N/A	N/
ASSESSMENT QUESTIONS	F	Requirements		Number Ma or m	Service Service Service	
7. PRODUCT REALIZATION		Allen A		neite uitte		
7.1 Planning of product realization	in.		33 (M)		30, 1 ,0 (6), 1 ,0 (7)	
01 Does the organization plan and develop the processes needed for product realization?	6 7 7 8 8 8 8 8		/		in plan	
(see 4.1).  02 Is planning of product realization consistent with the requirements of the other processes of the	e.		/		1.480 1.750 1.750 1.750 1.750 1.750	
quality management system (see 4.1) ?						
03 In planning product realization, does the organization determine the following, as appropriate:	v				A Service	
<ul><li>a) qualify objectives and requirements for the product?</li><li>b) the need to establish processes, documents, and provide resources specific to the</li></ul>			1	1		
product?  c) required verification, validation, monitoring, inspection and test activities specific to the	e					
product and the criteria for product acceptance?	, işt	1.5	*****			
d) records needed to provide evidence that the realization processes and resulting produc	ct	P	:	₹		
meet requirements (see 4.2.4)?  e) the identification of resources to support operation and maintenance of the	•					
e) the identification of resources to support operation and maintenance product?						
04 Is the output of this planning in a form suitable for the organization's method of operations?			1			_
Dijective evidence assessed / Observations / Comments / N/A explanation						
Notice la Landales		•		٠	?	rg.
Don't Lens for Assy for 4VGS						
Sampled widone of planning per TPS (Test Br	epi	nation	$\mathcal{F}$	)crum	<i>‡</i> )	
TPS-AVGS-5D73-031				•	ž	
TPS-AUGS-5D73-026					ري معرف (42) مورون	
TPS- AUGS-SD13-025			•		pithe Julia i	
TP5- AUGS-5073-042						
TP5-AVGS-8973-038			-			
				·		
Vode II - Reviewed Project Plan SSNPO-J481.1	1	<u>,</u>	0 6	1.		
Reviewed pertinent section of plan for fulfilling reg	10	, und	rd	4	N.	
The standard Court of the Market Mark	u Ca	آ بر م <i>ا</i>	atri	unt	/len	
With neurous, resoldy person, configuration to		· -			AAI	ġ
Oth Reviews, Messelly Reviews, Configuration A Nort'of Aug'of SSNPO-NC-0015		5	5N	PO-NC	-0010	G
With Reviews, Marchy Reviews, Configuration of Nort'ay Aug 'at SSNPO-NC-0015  15 PT Project - Reviewed 15 PT - PLAW-1001 June ay  Related Find Report DCN No. SSP-04-105 - Sol			5.44.Ed	MACO		

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QUALITY SYSTEM QUESTIONNAIRE		an energy and energy and energy		THE STATE OF THE S	
ASSESSMENT QUESTIONS	KEY Requirements	s	CAR Number	N/A	N/E
	Requirements		Ma or mi		100
7.2 Customer-related processes	200 (200 ) 200 (200 ) 200 (200 )	Maty par Magant Magan			(
7.2.1 Determination of requirements related to the product	W.			1945 1844	
<ul> <li>05 Does the organization determine:</li> <li>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities?</li> <li>b) requirements not stated by the customer but necessary for specified or intended use, where known?</li> </ul>	М	V			
c) statutory and regulatory requirements related to the product ? and	2000 mm		<u> </u>	ya.	1
d) any additional requirements determined by the organization?		, , , , , , , , , , , , , , , , , , ,		\$	
7.2.2 Review of requirements related to the product	· · · · · · · · · · · · · · · · · · ·	1,	***	r e r	
06 Does the organization review the requirements related to the product?		1			
<ul> <li>07 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that (1):</li> <li>a) product requirements are defined?</li> <li>b) contract or order requirements differing from those previously expressed are resolved?</li> <li>c) the organization has the ability to meet the defined requirements? And</li> </ul>	P				
d) risks (e.g., new technology, short delivery time scale) have been evaluated?					ļ
08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2)?					
09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance?					
10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?	P				
Note: In some situations, such as internet sales, a formal review is impractical for each order. Instead product information such as catalogues or advertising material.	the review	can cove	r the rele	evant	
7.2.3 Customer communication					
Does the organization determine and implement effective arrangements for communicating with customers in relation to:  a) product information?  b) enquiries, contracts or order handling, including amendments? and  c) customer feedback, including customer complaints?		i			
Guidance Notes					一

Check that all affected functions are involved in the review

Give examples

Objective evidence assessed / Observations / Comments / N/A explanation Revived custome communication for NODE II, ISPT, Dant project custome interfaces, determination agreement a oustonie requirements, rish assessment, confirmation of product requirement and associated record -Project Plans, DM Plans, CAM. Plans, TPS Docis. - deliverables

> S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE			1915.2. 1937 pe
ASSESSMENT QUESTIONS	KEY S Requirements	CAR N/A Number Ma or mi	N/E
7.3 Design and development	and the second s		
7.3.1 Design and development planning			
12 Does the organization plan and control the design and development of product ?		7 dr. 7 dr. 7 gr. m.	K
13 During the design and development planning, does the organization determine:  a) the design and development stages (1)?  in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,	M		
b) the review, verification and validation that are appropriate to each design and development stage? and c) the responsibilities and authorities for design and development?		200 mg/m	K
<ul> <li>Where appropriate, due to complexity, does the organization give consideration to the following activities:         <ul> <li>structuring the design effort into significant elements?</li> </ul> </li> <li>for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements?</li> </ul>			1
Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?		- /	4
16 Is planning output updated, as appropriate, as the design and development progresses?		-	+
17 Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements (2)?	Р	12 6	e le
7.3.2 Design and development inputs		· · · · · · · · · · · · · · · · · · ·	
Are inputs relating to product requirements determined and are records maintained (see 4.2.4)  (3) ?  Do these inputs include:	M	-200 01 02 04 04 04 04 04 04 04 04 04 04 04 04 04	
<ul> <li>a) functional and performance requirements?</li> <li>b) applicable statutory and regulatory requirements?</li> <li>c) where applicable, information derived from previous similar designs? and</li> <li>d) other requirements essential for design and development?</li> </ul>		3	
19 Are these inputs reviewed for adequacy?		500	
20 Are requirements completed, unambiguous and not in conflict with each other?		and the second	4

#### Guidance Notes

1) Give at least an example of a completed design & development plan, or an example of one in progress, that identifies the planning of tasks and key events.

2) Give an example

3) Review applicable input data (give examples)

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE		are de la companya de	4-1965 S - 1076 M - 1076 M - 1076 M - 1076 M		
ASSESSMENT QUESTIONS	KEY Requiremen	1" S 115	CAR Number Ma or mi	N/A	N/E
7.3 Design and development (continued)		Aller Approximate California California	700 Y S 200 Y S 200 Y S		
7.3.3 Design and development outputs			wig. Was		
21 Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release?			Continued to the contin		V
Do the design and development outputs:  a) meet the input requirements for design and development?  b) provide appropriate information for purchasing, production and for service provision?	M	# 45 / # 45 / # 45 / # 10 / # 10 /	9.500 10.		
c) contain or reference product acceptance criteria? d) specify the characteristics of the product that are essential for its safe and proper use? and e) identify key characteristics, when applicable, in accordance with design or contract requirements?					
23 Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization; for example:  - drawings, part lists, specifications?  - a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product?  - information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product?	M	ार सम्ब			X
7.3.4 Design and development review					
At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to (1):  a) evaluate the ability of the results of Design and development to meet requirements?  b) identify any problems and propose necessary actions? and	M				· <b>V</b>
c) authorize progression to the next stage?		+			<b>-</b> ∕∱
25 Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed ?				- 0, ,,,	V
26 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)?	,				V
7.3.5 Design and development verification					
27 Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements?					V
28 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)?					V
Note: Design and/or development verification may include activities such as:  - performing alternative calculations - comparing the new design with a similar proven design, if available - undertaking tests and demonstrations, and - reviewing the design stage documents before release.				-	

Guidance Notes

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Give evidence of reviews

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Objective evidence assessed / Observations / Comments / N/A explanation

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	ASSESSMENT (		Service of the second services	Water 1	KEY Requireme	S	CAR Number Ma or mi	N/A N/I
7.3 Design and dev	elopment (contin	ued)	and	14.5 14.5 14.5 14.5 14.5 14.5 14.5 14.5	Artender (n. 20. Artender (n. 20.) Artender (n. 20.)	ing mg. Mg. min	100 mg	The state of the s
7.3.6 Design and develo		e in the second	and the second s	- 6 (A) - 6 (A)			71. 11.776. :	Tight years of
<ol> <li>Is design and development (see 7.3.1) to ensure that the specified application or inte</li> </ol>	validation performed ne resulting product is	capable of n	ce with planned are neeting the require	rangements ments for the	Р			
Wherever practicable, is va     Product ?	alidation completed pri	or to the deli	ivery or implement	ation of the			West	(
Are records of the results of	of validation and any n	ecessary ac	tions maintained (s	see 4.2.4) ?				- (
Note: -Design and/or development validation is normally perform -Validation is normally perform -Validation is normally perform -Multiple validations may be pe	ed under operating co ed on the final produc	nditions. t, but may bi	e necessary in the		orior to produ	uct comp	eletion.	
7.3.6.1 Documentation of o	design and/or develo	pment veril	fication and valid	ation		`\ .		
2 At the completion of des reports, calculations, tes specification requiremen	ign and/or developm t results, etc., demon	ent, does ti strate that	ne organization e the product defin	nsure that	M		·	1
	elopment verification						· · · · · · · · · · · · · · · · · · ·	
3 Where tests are necessar controlled, reviewed, and a) test plans or specific used, define test objected acceptance criteria? b) test procedures describe recording of the recording of the requirements of the other acceptance criteria.	documented to ensi- ations identify the pre- ectives and condition cribe the method of results? tion standard of the p the test plan and the t	re and pro roduct being ns, parame operation, n product is s	ve the following ( g tested and the least to be record the performance submitted for the	1): resources bein ed, and relevar of the test, an test?	n	-	-	
Guidance Note  (1) Give an example of a qua	alification report			-			• • • • • • • • • • • • • • • • • • • •	». •
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QUALITY SYSTEM QUESTIONNAIRE		
ASSESSMENT QUESTIONS	KEY S Requirements	CAR N/A Number Ma or mi
7.3 Design and development (continued)	Harris galliga Allendar Allendar Allendar	166 166 166
7.3.7 Control of design and development changes		
34 Are design and development changes identified and records maintained?		- and the last
35 Are the changes reviewed, verified and validated, as appropriate, and approved before implementation (1)?	P	The second secon
36 Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered?	P	
37 Does the organization's change control process provide for customer and/or regulatory		
authority approval of changes, when required by contract or regulatory requirement?	4, 11	Weight 1
Records of the results of the review of changes and any necessary actions maintained (see 4.2.4)?		
		The Richard Control of the Control

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#### **Guidance Note**

1) Give an example

Objective evidence assessed / Observations / Comments / N/A explanation

S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

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	QU	ALITY S	SYSTEM QUE	ESTIONN	AIRE	The Maria Control of the Maria			A Table 1	
Apple	ASSESSM	IENT QUES	STIONS		SALA II.	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purcha	sina	172	and and	# 1 / 1 / 1 / 1 / 1 / 1 / 1 / 1 / 1 / 1	singulare Propinsi	regional control			in the second	ologijan Stantan
	sing process	74				- 1 m 1		Við:		200
9 Does the orga	nization ensure that purcha	sed product	conforms to specifi	ed purchase		P				C
0 Is the type and upon the effect	extent of control applied to to of the purchased product or	n subseque	nt product realization	n or the final pr	oduci /	14 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)				\\ \mathbb{\nu}
is the organiz	ation responsible for the	quality of a	ıll products purcha	sed from sup	oliers,	1985		ing to		V
including cus	omer-designated sources	5 ?					1 10 10 7			
2 Does the orga	nization evaluate and select the organization's require	t Suppliers I	pased on their ability	to supply prod	luct in			district A		V
accordance will  3 Are criteria for	selection, evaluation and re	-evaluation	established?	14 P				N. I.		V
4 Are records of maintained (se	he results of evaluations ar	nd any nece	ssary actions arising	g from the eval	uation .	rikan ili a r		*	• .	L
15 Does the orga	nization :	1.2				M	1	****		\ P
a) Maintain	a register of approved S									
a hasis f	ally review Suppliers perfor establishing the level o	of controls t	to be impiemented	(2) ?				<i>:</i> -		
c) Define th	e necessary actions to ta ents ?	ake when d	lealing with Suppli	iers that do n						
d) Ensure v	rhere required that both I special process sources	s ?						•		
al Engura	hat the function having has the authority to disap	a respons	ibility for approvi use of sources ?	ing Supplier	quaiity					

# **Guidance Notes**

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Review current list of approved Suppliers

Review suppliers performance / measurement system (e.g.: supplier rating, etc.)

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Objective evidence assessed / Observations / Comments / N/A explanation

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		QUALITY	SYSTE	<b>II QUEST</b>	IONN	IAIRE	A STATE OF THE STA				ya ter Yaya Kana Kaya		
propositi Aldia	ASSE	SSMENT QU	ESTIONS				KEY Requirem	ents S	N	CAR lumber la or mi	N/A	N/E	
7.4	Purchasing (continued)	10 (10 ) 10 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	and the second s	Signatura protesta de Obres de	(6) (7)	July 1	ANDE THE BURNESS		(fri	ik (il) (il) iki		Caretar Support	(
7.4.2	Purchasing information	#'apr. 1917	A Made				er Wingliere Filosoph	<del>19</del> 0	agal .			的智慧。 《音音》	
	es purchasing information describe propriate (1) :	the product to	be purchased	8	nere		P	1 al				1	/
a)	requirements for approval of produ	ıct, procedure	es, processes	and equipmen	nt ?								
b) c)	requirements for qualification of po-	445	1946 1960 1960 1960 1960 1960 1960		p. H. C.		10 (10 (10 (10 (10 (10 (10 (10 (10 (10 (					¥/	
e)	the name or other positive ident drawings, process requirement data? requirements for design, test, es acceptance by the Organization	s, inspection xamination, i	instructions	and other rei	levant te	echnical							
f)	requirements for test specimens conditions) for design approval						41-42 E			3 .			
g)	requirements relative to :									ا ہے		1	
•	- supplier notification to Organ	nizationr of n	onconformin	g product?	and							1	
	- arrangements for Organization	onr approval	of supplier n	onconformin	g mater	ial ?			ļ .	. "		1	
h)	requirements for the supplier to process definition and, where re	-	-	•		t and/or				٠.	-		
i)	right of access by the organizati involved in the order and to all a			uthorities to a	all facili	ties				-			
	requirements for the supplier to requirements in the purchasing required?	flow down to documents,	o subtier supp including key	oliers the app characterist	licable ics whe	re	-					1	
47 Does	s the organization ensure the ac	dequacy of s	specified pure	chase requir	ements	prior						J	-
	eir communication to the suppl									•		V	

#### **Guidance Note**

1) Examine purchase orders that apply to several types of procurement.

Objective evidence assessed / Observations / Comments / N/A explanation

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S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action NA: Not applicable - N/E: Not evaluated - P: Product - M: Management

	QUALITY SYSTEM QUESTIONNAIRE	W- 12-	W. W.		
	ASSESSMENT QUESTIONS	KEY Requirements	S CAR Number Major	er an inch	N/E
7.	4 Purchasing (continued)	- 1965 <u>- 1965 -</u>	50180 - 1 501 - 1 501 - 1	gladinos .	
7.4	4.3 Verification of purchased product	₩. <u>.</u>	1.4	10.00	
	Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification?	P ***			
49	Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure?				V
50	Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications (1)?  Does the organization periodically validate test reports for raw material (1)?				2
51					
52	Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained (1)?				V
53	Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of				1
54	product release in the purchasing information?  Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements?			:	V
55	It is ensured that verification by the customer is not used by the organization as evidence of effective control of quality by the supplier (it does not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer)?				

# **Guidance Note**

1) Give an example

Objective evidence assessed / Observations / Comments / N/A explanation

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	QUALITY SYSTEM Q	UESTIO	NNAIRE	1. Pri			20 (1976) No. 1
	ASSESSMENT QUESTIONS			KEY Requiremen	s s	CAR Number Ma or mi	N/A N/E
7.5	Production and service provision	10	Tark	6.	4/4	1000 C	Tapes .
7.5.1	Control of production and service provision			(C.).		W. William	
56 Do	es planning consider, as applicable :  the establishment of process controls and development key characteristics have been identified  the identification of in-process verification points when conformance cannot be performed at a later stage of re-	adequate v		P			\ \ \
·	the design, manufacture, and use of tooling so that var be taken, particularly for key characteristics, and		rements can		Sinday.		4
	- special processes (see 7.5.2).	V as a constant	3.5		S. Corp.	1	
cor Do a) b)	es the organization plan and carry out production and service positions (1).  these controlled conditions include, as applicable:  the availability of information that describes the characteristics of the availability of work instructions, as necessary?						\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\
c) d)	the use of suitable equipment? the availability and use of monitoring and measuring devices?			3.7	24.00	and the second second	e,,
ˈe) f)	the implementation of monitoring and measurement? the implementation of release, delivery and post-delivery activities	s?:					
g)	accountability for all product during manufacture (e.g., parts nonconforming product) ?	quantities,	r 1,5	P			
h)	evidence that all manufacturing and inspection operations had planned, or as otherwise documented and authorized?						. /
i)	provision for the prevention, detection, and removal of foreign	gn objects ?		Р			
j)	monitoring and control of utilities and supplies such as electricity and chemical products to the extent they affect pro	oduct quality	?? and			-	
. <b>k</b> )	criteria for workmanship, which shall be stipulated in the cleeg., written standards, representative samples or illustration	earest pract ns) ?	ical manner	1.			
Guida	ance Notes						
	the Part Number(s) used for this review						

Not included in this Dukweillance Actually Objective evidence assessed / Observations / Comments / N/A explanation

> S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE			en e		
ASSESSMENT QUESTIONS	Require		S CAR Numb Ma or	er	A N/E
7.5 Production and service provision (continued)	in the second se		ging mut	in the second	114
7.5.1.1 Production documentation	(4) (4)				12 f. J.
58 Are production operations carried out in accordance with approved data?		an:			U
59 Does the data contain as necessary:  a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1)? and  b) a list of specific or non-specific tools and numerical control (NC) machine programs	P				1
required and any specific instructions associated with their use ?	7-5				6
7.5.1.2 Control of production process changes	Tage of the Second		46	· -	- <u> </u>
Are persons authorized to approve changes to production processes identified (1) ?	M				1
61 Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements?					L
62 Are changes affecting processes, production equipment, tools and programs documented?	Р				2
63 Are procedures available to control their implementation?					1
Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality?	Р				1
5.1.3 Control of production equipment, tools and numerical control (N.C.) machine program	ns	•			
55 Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures?	Р				V
Does validation prior to production use include verification of the first article produced to the design data/specification?	Р			-	1
7 Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage?					L
5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities	5		· <del></del>		
88 When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work?	М				V

### **Guidance Notes**

1) Clearly defined list or procedures

application of the

When clusted in this Descrettance Objective evidence assessed / Observations / Comments / N/A explanation

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S. Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable N/E: Not evaluated - P: Product - M: Management

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QUALITY SYSTEM QUESTIONNAIRE			
ASSESSMENT QUESTIONS	KEY Requirements	Ma or mi	N/A N/E
7.5 Production and service provision (continued)	71-5	and the second s	(
7.5.1.5 Control of service operations	W.		
Where servicing is a specified requirement, do service operation processes provide for:  a) a method of collecting and analyzing in-service data?  b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2)?  c) the control and updating of technical documentation?  d) the approval, control, and use of repair schemes (3) 2 and;			
e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities)?	Telescope (		(/
7.5.2 Validation of processes for production and service provision	s State	<u> </u>	4174.5 2
Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes	P		
any processes where deficiencies become apparent only after the product is in use or the service has been delivered) (4)?	**************************************		
Note: These processes are frequently referred to as special processes.	-		
1 Does validation demonstrate the ability of these processes to achieve planned results?	.,. •		
<ul><li>Has the organization established arrangements for these processes including, as applicable:</li><li>a) defined criteria for review and approval of the processes?</li></ul>	M		$ \zeta $
-qualification and approval of special processes prior to use ?			
b) approval of equipment and qualification of personnel ?		-	4
c) use of specific methods and procedures ?			
- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?		egs (	
d) requirements for records (see 4.2.4)?			
· · · · · · · · · · · · · · · · · · ·	į.		<b>V</b>

# **Guidance Notes**

- 1) Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports
- 2) Review evidence of implementation of corrective and preventive actions.
- 3) Review evidence of what has been assessed (e.g.: maintenance manual, repair manual, information to customer)
- 4) Verify the existence of list of special processes.

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5) Give examples

Objective evidence assessed / Observations / Comments / N/A explanation

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	QUALITY SYSTEM QUESTIONNAIRE		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
	ASSESSMENT QUESTIONS	KEY Requirements	S CAR Number Ma or mi	N/A N/E
7.	Production and service provision (continued)	17 - 40 19 (178)	min min sa Min min sa Min min sa	1000 m 1000 m 1000 m 1000 m
7.5	i.3 Identification and traceability		and the second	997
73	Where appropriate, has the organization identified the product by suitable means throughout product realization?			L
74	Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration?			
75	Has the organization identified the product status with respect to monitoring and measurement requirements?			4
76	When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1) ?			L
77	Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4)?			L
78	According to the level of traceability required by contract, regulatory, or other established requirement, does the organization's system provide for (2):	P		4
	a) identification to be maintained throughout the product life ?			
	b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch?		get to save	
	c) in any assembly, the identity of its components and those of the next higher assembly to be traced?			
	d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved?			L
Vote	In some industry sectors, configuration management is a means by which identification and tr	aceability is r	naintained.	

'.5. <sub>4</sub>	Customer property			變
79	Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (3)?		7.	L
80	Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product?			- L
81	Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer?			L

Note: Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection.

# **Guidance Notes**

1) Give examples of method(s) used

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te distribution provides

Sald allows

- 2) Give examples of traceability level applied (up and down)
- 3) Identify types of product supplied by the customer.

Objective evidence assessed / Observations / Comments / N/A explanation

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Objective evidence assessed / Observations / Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE		
ASSESSMENT QUESTIONS	KEY S CAR Requirements Numb Ma or	er
7.5 Production and service provision (continued)	on the second of	f
7.5.5 Preservation of product	The second se	Y
82 Does the organization preserve the conformity of product during internal processing and delivery to the intended destination?		
83 Does the preservation include identification, handling, packaging, storage and protection?		11
84 Does preservation also apply to the constituent parts of a product?		
85 Does preservation of product also include, where applicable in accordance with product	P	
specifications and/or regulations, provisions for :  a) cleaning ?		
b) prevention, detection and removal of foreign objects?  c) special handling for sensitive products?		
d) marking and labeling including safety warnings ?		
e) shelf life control and stock rotation ? f) special handling for hazardous materials ?	7000 1111	. 4
86 Does the organization ensure that documents required by the contract/order to	white the second of the second	1
accompany the product are present at delivery and are protected against loss and deterioration?	1 14 2 2	

Objective evidence assessed / Observations / Comments / N/A explanation

not included in this Durwillance activity

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mī: Minor corrective action
NA: Not applicable - N/E: Not evaluated - P: Product - M: Management

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	QUALITY SYSTEM QUESTIONNAIRE			UNITY		79 An	
	ASSESSMENT QUESTIONS	KEY Requirement	S	CAR Number Ma or mi	N/A	N/E	
7	.6 Control of monitoring and measuring devices		al imite		:	and the	_
87	Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1) (1)?	11.		34 (i.) 14 (i.) 15 (i.)		Ü	1
No	Does the organization maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria?  ote: Monitoring and measuring devices include, but are not limited to: test hardware, test					5	
als	oftware, automated test equipment (ATE) and plotters used to produce inspection data. It is includes personally owned and customer supplied equipment used to provide evidence is product conformity.					(	7
	Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?			1.0, 		レ	
90	Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out?	. '	-	1 - 15 <u>-</u>		L	-
91	Where necessary to ensure valid results, is measuring equipment:				4		
	a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (2)?				ert Sagar Hali		
	b) adjusted or re-adjusted as necessary? c) identified to enable the calibration status to be determined?					1	
	d) safeguarded from adjustments that would invalidate the measurement result?						
	e) protected from damage and deterioration during handling, maintenance and storage?					(	
	f) recalled to a defined method when requiring calibration ?					1	
92	Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements?					1	/
93	Does the organization take appropriate action on the equipment and any product affected ?	Р				1	/
94	Are records of the results of calibration and verification maintained (see 4.2.4)?	4.				1	/
95	When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed?	P				L	ر
96	Is this undertaken prior to initial use and reconfirmed as necessary?					1	/

# **Guidance Notes**

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1) Review that the organization has a process for ensuring the capability of measurement system (e.g. Interval Analysis, Resolution Analysis, Gage Repeatable & Reproducibility, etc.)

2) Ensure the links to the recognized international / national standard.

Objective evidence assessed / Observations / Comments / N/A explanation

Modern Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

Objective evidence assessed / Observations / Comments / N/A explanation

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Objective evidence assessed / Observations / Objective / Ob

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QUALITY SYSTEM QUESTION	ONNAIRE	
ASSESSMENT QUESTIONS	KEY Requirements	CAR N/A N/E Number Ma or mi
8 MEASUREMENT, ANALYSIS AND IMPROVEMENT	And the second s	
8.1 General		
O1 Does the organization plan and implement the monitoring, measurement, improvement processes needed (1):  a) to demonstrate conformity of the product?  b) to ensure conformity of the quality management system, and?  c) to continually improve the effectiveness of the quality management system?	analysis and M	
02 Does this include determination of applicable methods, including statistical technic extent of their use?	niques, and the	

Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- -design verification (e.g., reliability, maintainability, safety);
- -process control:
  - selection and inspection of key characteristics;
  - · process capability measurements;
  - statistical process control;
  - design of experiment;
- inspection matching sampling rate to the criticality of the product and to the process capability ;
- -failure mode and effect analysis.

#### **Guidance Notes**

1) Give examples of data

Objective evidence assessed / Observations / Comments / N/A explanation

on Dart contract project observed indications of planning for Measurement + Menitoring of product.

TPS-AUGS-SD73-031, 024, 025, 042, and 038.

all provide in direction of approval + full completion.

OWI - 5073-0WI-001 Baselin

observed NC processing - NC # RROOM 13794.

RWK- SquawK-S8264

100 % inspection of product.

15 PT - PLAW-1001 - Solar Sail Propulsion TAG Final Report

Nodes I Project - Reviewed Embedded requirements of Project Clan pon: 3.34.2.2.4, 3.3.7.2.6.2., 8.3.11.1.K-m - Verfeed Compliances Notice

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	Requirements	Number Ma or mi		
8.2 Monitoring and measurement (continued)	Part Control of the C	Control of the contro		(1)
8.2.1 Customer satisfaction				1100
03 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements (1)?		3		
04 Are the methods for obtaining and using this information determined?	1.000 S	>		13.54 9.44
8.2.2 Internal audit As poor week of MR 1280.6	There is, it is a second of the second of th		13 Traff 1. 94-31	
05 Does the organization conduct internal audits at planned intervals to determine whether the quality management system (2):  a) conforms to the planned arrangements (see 7.1), to the requirements of this international Standard and to the quality management system requirements established by the organization? and	M			
b) is effectively implemented and maintained?	5	Jan Marine Street Co. 18		
06 Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?	5	>		
07 Is the audit criteria, scope, frequency and methods defined?	5	,		
08 Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process (3)?	S	,		:
09 Does the organization ensure internal auditors do not audit their own work?	5	1,		
10 Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure?	3			
1.1 Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes?	M 5			
12 Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2) (4)?	S	,		
13 Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements?	S	,		
14 Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organization performance?	S			
15 Do internal audits also meet contract and/or regulatory requirements?	15	,	$\bot$	
Guidance Notes  1) Give examples of how customer's satisfaction is measured, committed, and acted upon.  2) Review of audit plan (status of the previous year and progress of the current year). Julius (Check the list of approved auditors.  3) Check the list of approved auditors.  4) Review type of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective actions.		-up). Ulk	ife	18
Objective evidence assessed / Observations / Comments / N/A explanation	-	<i>a</i> .		
Sustance Satisfaction Welled to Customer Gedleville Pendit Plans identify relationship to regularieme res P50 2200 401,050 200401 all agric goldent	storethe practice	e Stan	ala U	'Li
Supermation Septem database Tundeng Succession September database Tundeng Previous Brusher	STENAU STENAU STENAU	main	tain	1 48
n alease.	(2) (1) (2) (2) (2) (2) (2) (2) (2) (2) (2) (2			
Tollow upg previous finding plufarmed	h in L	)/ n 4 n 1	x 5	/-
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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)	Lating These		Brand T	the first	
8.2.3 Monitoring and measurement of processes	and the second			in in the second	
16 Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes?	28 Maria			100 m	ν
17 Do these methods demonstrate the ability of the processes to achieve planned results ?			THE STATE OF THE S	1,1,17%	V
18 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?			To the second		V
19 In the event of process nonconformity, does the organization (1)	P				V
a) take appropriate action to correct the nonconforming process ?					
b) evaluate whether the process nonconformity has resulted in product nonconformity?		,	1979 1975		V
and c) identify and control the nonconforming product in accordance with clause 8.3?	, <u>(</u> 400.0)				
8.2.4 Monitoring and measurement of product		#35 <sup>2</sup>			
20 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?	Р	4.			V
21 Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1)?		***			V
22 When key characteristics have been identified, are they monitored and controlled ?	P		x .		·V
23 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use ?					
24 Does the plan preclude the acceptance of lots whose samples have known nonconformities?					$\nu$
25 When required, is the plan submitted for customer approval ?					U
26 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities?	Р				V
27 Is evidence of conformity with the acceptance criteria maintained ?			1.1. 2		V
28 Do records indicate the person(s) authorizing release of product (see 4.2.4) ?					$\nu$
29 Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?					
			<del></del>		

#### Guidance Note

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1) Give examples of non conformity (product, process, ...).

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Objective evidence assessed / Observations / Comments / N/A explanation

Mutually and Living Divisional Comments / N/A explanation

Other Comments / N/A explanation

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ASSESSMENT QUESTIONS	KEY Requirements	S CAR N/A N/E Number Ma or mi				
8.2 Monitoring and measurement (continued)	tope A Light					
8.2.4.1 Inspection documentation						
30 Are measurement requirements for product or service acceptance documented?	144 C					
31 Does this documentation, which may be part of the production documentation, include:  a) Criteria for acceptance and/or rejection?  b) Where in the sequence measurement and testing operations are performed?  c) a record of the measurement results? and	P	7				
d) type of measurement instruments required and any specific instructions associated with their use ?		E				
32 Do test records show actual test results data when required by the specification or acceptance test plan ?						
33 When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements?		V				
8.2.4.2 First article inspection						
34 Does the organization's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result (1)?	P					

Guidance Note

1) Give examples of first article (new product and change).

Objective evidence assessed / Observations / Comments / N/A explanation

MA Explanation

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241794.0 27 77	QUALITY SYSTEM QUESTIONNAIRE				res is Williams
<i>019</i>	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number	N/A N/E
page.	A STATE OF THE STA	C   C   C   C   C   C   C   C   C   C		Ma or mi	ana a da Maria
8.3	Control of nonconforming product	30000000000000000000000000000000000000	1964.4. 1861.1	100	
<u>Note</u>	: The term "nonconforming product" includes nonconforming product returned from a	üstomer.	- 1		The state of the s
Kare,	A to a series of the series of	ÎP I	26 SQ . F	e i i jegova V i i i i jegova	
a	oes the organization ensure that product which does not conform to requirements is identified nd controlled to prevent its unintended use or delivery?				
36 A p	re the controls and related responsibilities and authorities for dealing with nonconforming roduct defined in a documented procedure?				V
а	oes the organization's documented procedure define the responsibility for review and uthority for the disposition of nonconforming product and the process for approving ersonnel making these decisions?				V
38 D	oes the organization deal with nonconforming product in one or more of the following ways by:  ) taking action to eliminate the detected nonconformity?	P			1
. Б	) authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?				
c)	taking action to preclude its original intended use or application?	j		in the	$\mathcal{L}$
39 D	oes the organization prevent dispositions of use-as-is or repair, unless specifically uthorized by the customer, if		1.0		K
	the product is produced to customer design ? or	-	ľ		
	the nonconformity results in a departure from the contract requirements ?				1 1
re	Unless otherwise restricted in the contract, is organization-designed product, which is controlled via a customer specification, dispositioned by the organization as-use-as is or epair, provided the nonconformity does not result in a departure from customer-pecified requirements?)				4
	product dispositioned for scrap conspicuously and permanently marked, or positively ontrolled, until physically rendered unusable ?	Р			
	re records of the nature of nonconformities and any subsequent actions taken, including oncessions obtained, maintained (see 4.2.4)?				$\mathcal{V}$
	hen nonconforming product is corrected, is it subject to re-verification to demonstrate informity to the requirements?				
43 W or	hen nonconforming product is detected after delivery or use has started, does the ganization take action appropriate to the effects, or potential effects, of the nonconformity?	Р			
or	addition to any contract or regulatory authority reporting requirements, does the ganization's system provide for timely reporting of delivered nonconforming product at may affect reliability or safety?	Р		1	
ne	nes notification include a clear description of the nonconformity, which includes as ccessary, parts affected, customer and/or organization part numbers, quantity, and te(s) delivered?				
Objec	etive evidence assessed / Observations / Comments / N/A explanation  Must milled in this is  Alticlety	Dece	!be	elle	rece

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	QUALITY SYSTEM QUESTIONNAIRE		
	ASSESSMENT QUESTIONS	KEY S Requirements	CAR N/A N/E Number Ma or mi
8.4	Analysis of data	7000 7000	Charles Control of Markets
su	pes the organization determine, collect and analyse appropriate data to demonstrate the itability and effectiveness of the quality management system and to evaluate where continual provement of the effectiveness of the quality management system can be made?	M	2
	es this include data generated as a result of monitoring and measurement and from other evant sources?	S	
	es the analysis of data provide information relating to:	S	e projection of the control of the c
— <del>a)</del> b)	customer satisfaction (see 8.2.1) (1) ?  conformity to product requirements (see 7.2.1) ?	\$	
c)	characteristics and trends of processes and products including opportunities for preventive action ? And	1	
d)	suppliers?		

#### Guidance Note

1) Give examples and check how the organization measures the effectiveness.

Objective evidence assessed / Observations / Comments / N/A explanation

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Trends Love Prevaluels and Suppliers are

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Covering throughout the Progressive

Management Love with Suppliers MAC, PMC,

MTM, ECLSS Project Sevenis

S: Satisfactory: CAR: Corrective action required – Ma: Major corrective action mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

ASSESSMENT QUESTIONS  8.5 Improvement  8.5.1 Continual improvement  49 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy quality objectives; audit results, analysis of data, corrective and preventive actions and management review?  8.5.2 Corrective action  50 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence (1)?  51 Are Corrective actions appropriate to the effects of the nonconformities encountered?  52 Is a documented procedure established to define requirements for:  a) reviewing nonconformities (including customer complaints)?  b) determining the causes of nonconformities?  c) evaluating the need for action to ensure that nonconformities do not recur?  d) determining and implementing action needed?  e) recording of the results of the action taken (see 4.2.4)?  f) reviewing corrective action taken?  g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause? and  h) specific actions, where timely and/or effective corrective actions are not achieveg?		ASSESSMENT QUESTIONS  ASSESSMENT QUESTIONS				
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# Annex A (informative)

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